

TEH LIN PROSTHETIC & ORTHOPAEDIC INC.

No. 7, Wu Chuan 7th Road, WuKu Industrial Park,
Taipei County, Taiwan R.O.C.

Telephone: 886-2-22991901 Fax: 886-2-22991030
E-mail: tlco@ms2.hinet.net <http://www.tehlin.com.tw>

SEP 24 2004

K042011

" 510(k) SUMMARY "

Submitter's Name: **TEH LIN Prosthetic & Orthopaedic Inc.**

No. 7, Wu Chuan 7th Road, WuKu Industrial Park, Taipei County, Taiwan
R.O.C.

Date summary prepared:

July 22, 2004

Device Name:

Proprietary Name: TEH LIN Power Scooter, TL-821
Common or Usual Name: Powered Scooter
Classification Name: Powered Scooter, Class II,
21 CFR 890.3860

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The TEH LIN Powered Scooter, TL-821 is an indoor / outdoor Powered Scooter that is battery operated. It has a base with four-wheeled with a seat. The movement of the Scooter is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically Powered Scooters, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

TEH LIN POWER SCOOTER TL-588(K022698)

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C.2 COMPARISON SUMMARY

(We place the related information for the predicate device in the following pages, including the visual appearance, 510k information on the FDA website, and the comparison and summary table.)

According to the above table that the intended use between two devices is the same. The **batteries** used are the same brand and same type that is certified by UL. The **control** systems for the two devices are same brand i.e., Penny & Giles for the two devices. The **recharge** for the two devices are used the same resource, HP8204A, and the recharger is certified by UL. Besides, the **foldable frame**, removable **arm type**, same **tires**, same **seat size**, same **warranty** on component and frame, and **back upholstery** are the same material that also be passed the resistance ignition test by SGS.

The overall dimensions, weight limit, and weight capabilities differences between two devices are small, and the dimensions for the new device are larger than those of the predicate device. The device of the smaller dimensions can be fitted into most of the ordinary car trunk.

The cruising range of the new device is 37 km and 40 km for the predicate device. This is mainly due to the fact that the batteries for the two devices are smaller. Certainly the real range depends on the practice environments, i.e., weight, surface, incline, and temperature. For the real life use, the two devices are substantially equivalent.

The safety climbing abilities for the two devices are different, the new device is 12° and 15° for the predicate device. We place the relevant specification of maximum climbing ability 12° in the owner's manual. The user's climb is not allowed to exceed 12° for the new device. In this sense the two devices are substantially equivalent.

The maximum speed is 5.6 mph for the new devices and 5 mph for the predicate device. The throttle tiller can continuously adjust the speeds. The operators can set the adequate speed according to their feeling and need, i.e., outdoor or indoor. This means the two devices have the same safety and hazard.

Based on the above the information and the analysis, we know that the subject device and the predicate device have the same intended use, the same technological aspects and only minor differences exist. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.

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Summary for substantial equivalence comparison:

The intended use between the two devices is the same. The **batteries** used are the same brand and same type that is certified by UL. The **control** systems for the two devices are same brand i.e., Penny & Giles for the two devices. The **recharge** for the two devices are used the same resource, HP8204A, and the recharger is certified by UL. Besides, the **foldable frame**, removable **arm type**, same **tires**, same **seat size**, same **warranty** on component and frame, and **back upholstery** are the same material that also be passed the resistance ignition test by SGS.

Thus the same safety level for the two devices is assured. The major differences existing of the two Power Scooters are the different overall dimension, weight limit, weight capabilities, climbing angle, cruising range, and maximum speed between the two devices. Based on the above the information and the analysis, we know that the subject device and the predicate device have the same intended use, the same technological aspects and only minor differences exist. So the new device is substantially equivalent to the predicate devices in this aspect.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 24 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Teh Lin Prosthetic & Orthopaedic, Inc.
C/o Dr. Ke-Min Jen
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, China (Taiwan) 300

Re: K042011

Trade/Device Name: Teh Lin Power Scooter, TL-821
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: August 31, 2004
Received: September 7, 2004

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

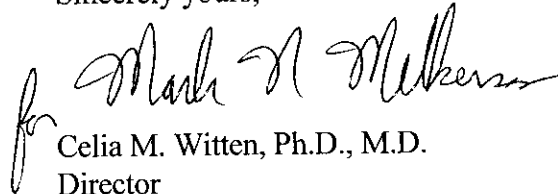
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Milkens". To the left of the signature is a small, stylized "for" written vertically.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (K) NUMBER (IF KNOW): TBA

DEVICE NAME: TEH LIN POWER SCOOTER, TL-821

INDICATIONS FOR USE:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use _____

AND/OR

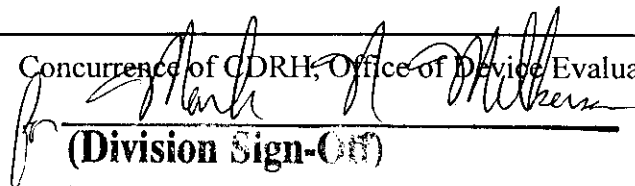
Over-The-Counter Use √

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K042011